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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,903	01/08/2007	Richard Head	024219-0105	3340

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EXAMINER	
YU, HONG	

ART UNIT	PAPER NUMBER
1613	

MAIL DATE	DELIVERY MODE
09/15/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,903	HEAD ET AL.	
	Examiner	Art Unit	
	HONG YU	1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7--18* is/are pending in the application.

4a) Of the above claim(s) *1-4 and 9-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5, 7, 8, and 15-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

The amendment file on 07/06/2010 is acknowledged. Claim 6 has been canceled and new claim 18 has been added. Claims 5, 7, 8, and 15-18 are under examination in the instant office action.

Rejections remained

The following rejections of the claims are remained for reasons of record and the following. In addition, new claim hereby is included in the rejections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5, 7, 8, 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Sair et al. (US 4,230,687).

Sair et al. meets all of the limitations of claims 5, 7, 8, 15, and 18. Sair et al. discloses an encapsulation material comprising casein as a protein and modified starch Capsul as a treated carbohydrate (claim 1 and column 9, line 24-28). Sair et al. is silent about the modified starch as carbohydrate being treated to make emulsions of the

encapsulation material stable and to increase the number of sugar reducing groups in the carbohydrate. The treated carbohydrate recited in the disclosure of the instant specification is Capsul (page 7, line 30) which is the same as the modified starch (Capsul) disclosed by Sair et al., thus the modified starch disclosed by Sair et al. is necessarily treated to make emulsions of the encapsulation material stable and to increase the number of sugar reducing groups in the carbohydrate. Sair et al. is silent about the encapsulation material releasing the therapeutic and nutritional agents in predetermined location in the gastro-intestinal tract. The encapsulation material disclosed by Sair et al. comprises the same components as the encapsulation material recited in the instant claim, thus the encapsulation material disclosed by Sair et al. would necessarily posses the same release property as that of the encapsulation material recited in the instant claim.

Sair et al. meets all of the limitations of claim 16. Sair et al. discloses the said encapsulation material being dried to form powder (column 24, line 52 and 53).

Sair et al. meets all the limitations of claim 17. Sair et al. discloses a method of making encapsulation material comprising dissolving casein in water then mixing the casein solution with essential oil (example 4: column 12, line 40-51). Although the method disclosed in prior art is not exactly the same as the claimed the method, both methods share the same general procedure as mixing water solution with oil to form emulsion: the prior art does not have the step of dissolving active in oil since oil itself is the active. Thus, while the claimed composition comprises the same components as the composition disclosed in prior art, the materials produced by both procedures are

necessarily the same and would be capable of releasing active in predetermined location in the gastrointestinal tract unless proven otherwise. Furthermore, the limitation in claim 17 is a product-by-process limitation. The determination of patentability of a product-by-process claim is based on the product itself, not its method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. Both of the encapsulation material disclosed by Sair et al. and the encapsulation material recited in the instant claim comprise the same components with the components being physically mixed, thus the product disclosed by Sair et al. would necessarily be the same as the product recited in the instant claim. The burden is shifted to the applicant to provide evidence to demonstrate that the structure of the claimed encapsulation material resulted from the said process is different from that of the encapsulation material disclosed in the prior art. See MPEP 2113 [R-1].

Response to Applicants' arguments:

Applicants argue that because of the difference between the claimed procedure of making the material and the procedure disclosed by Sair et al. the material will not be the same as the material disclosed by Sair et al. and the melting procedure according to Sair et al. would likely to have adverse effect on the shelf-life of the disclosed material

However, this argument is not deemed persuasive. As presented by the examiner in the 102 rejection above, although the method disclosed in prior art is not exactly the same as the claimed method, both methods share the same general procedure. Thus, while the claimed composition comprises the same components as

the composition disclosed in prior art, the materials produced by both procedures are necessarily the same and would be capable of releasing active in predetermined location in the gastrointestinal tract unless proven otherwise. Furthermore, the limitation in claim 17 is a product-by-process limitation. Please note that in product-by-process claims, "once a product appearing to be substantially identical is found and a 35 U.S.C. 102 rejection is made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113. This rejection under 35 U.S.C. 102 is proper because the "patentability of a product does not depend on its method of production." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). Applicant merely argues that the product is different and nothing has been shown otherwise. Applicant argues that "Sair's methodology is likely to affect adversely the shelf life of the encapsulated material" and "Sair's method does not result in the same type of care/shell type protective encapsulation that he claimed invention achieves." However, nothing has been shown to substantiate this. From MPEP 716.01(c) II: The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Furthermore, Sair et al. disclose the material being storage-stable (claim 1).

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brain-Yong Kwon can be reached on 571-272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. Y./
Examiner, Art Unit 1613
/Ernst V Arnold/

Primary Examiner, Art Unit 1613